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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/749,728	12/28/2000	Akihiro Umezawa	766.43	6784

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NEW YORK, NY 10112

EXAMINER

SHUKLA, RAM R

ART UNIT	PAPER NUMBER
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1632

21

DATE MAILED: 08/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/749,728

Applicant(s)

UMEZAWA ET AL.

Examiner

Ram R. Shukla

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,6-63 and 78-91 is/are pending in the application.
- 4a) Of the above claim(s) 47-63 and 78-91 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 6-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 19.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Response filed 6-20-03 has been received and entered.
2. Claims 2-5 and 64-77 have been cancelled.
3. Claims 47-63 and 78-91 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 17.
4. This application contains claims 47-63 and 78-91, drawn to an invention nonelected with traverse in Paper No. 17. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
5. Claims 1, 6-46 are under consideration.

### ***Priority***

6. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on Pat Hei.11-372826 filed 12-28-1999 and PCT/JP00/01148, filed 2-28-00. It is noted, however, that applicant has not filed a certified copy of these applications as required by 35 U.S.C. 119(b).

Acknowledgement is made to applicants' response that they are trying to obtain the priority documents.

### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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8. Claims 1 and 7-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Shi et al (Blood 92:362-367, 1998)).

Shi et al teaches derivation of endothelial cells from bone marrow cells and growth and differentiation of the bone marrow cells in presence of different growth factors and expression of markers by these cells (see the entire article). It is noted that the claims are drawn to a cell that has a potential to differentiate into different at least a vascular endothelial cell, the cells of Shi et al will meet the limitations since all the markers recited will be inherent properties of the cells because these are bone marrow cells and based on the condition of culture will differentiate into different cell type. Therefore, the claimed invention is anticipated by Shi et al.

9. Claims 1 and 6-46 are rejected under 35 U.S.C. 102(a) as being anticipated by Makino et al (Journal of Clinical Investigation. 103:697-705, 1999).

This art teaches that cardiomyocytes can be generated from marrow stromal cells in vitro (see the entire article). Therefore, the claimed invention is anticipated by Makino et al.

### ***Response to Arguments***

Applicant's arguments filed 6-20-03 have been fully considered but they are not persuasive. Applicants' arguments that the stem cells of Shi and Makino et al are not multipotent cells are not persuasive because both these arts teach that marrow stromal cells differentiate into endothelial cells or in cardiomyocytes. It is noted that the invention as instantly presented only requires that the cell differentiates into at least cardiomyocyte or other cells. Therefore, claimed invention is anticipated by Shi et al or Makino et al.

10. Claims 1 and 6-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Tomita et al (Circulation 100 (Suppl II) 247-256, 1999).

Tomita et al teaches improvement of damaged heart function after transplantation of bone marrow cells (see the entire article). Additionally, Tomita

et al discusses that bone marrow has multipotential progenitor cells which can differentiate into muscle, cartilage, bone, fat and tendon (see the second paragraph in the left column on page 247). It is noted that the claims are drawn to a cell that has a potential to differentiate into different at least a vascular endothelial cell, the cells of Tomita et al will meet the limitations since all the markers recited will be inherent properties of the cells because these are bone marrow cells and based on the condition of culture will differentiate into different cell type. Therefore, the art of Tomita et al anticipates the invention of claims 1 and 6-46.

11. Claims 1 and 6-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Ferrari et al (Science 279:1528-1530, 1998)).

Ferrari et al teaches teaches bone marrow derived myogenic progenitors (see the entire article). The art further teaches that bone marrow derived mesenchymal cells which differentiate into bone, cartilage and lung parenchyma can differentiate into contractile myotubes (see the second paragraph in the left column on page 1528). It is noted that the claims are drawn to a cell that has a potential to differentiate into different at least a vascular endothelial cell, the cells of Ferrari et al will meet the limitations since all the markers recited will be inherent properties of the cells because these are bone marrow cells and based on the condition of culture will differentiate into different cell type. Therefore, the art of Ferrari et al anticipates the invention of claims 1 and 6-46.

12. No claim is allowed.


Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory

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action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for TC 1600 is (703) 703-872-9306. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3413.



**RAM R. SHUKLA, PH.D.**  
**PRIMARY EXAMINER**

Ram R. Shukla, Ph.D.  
Primary Examiner  
Art Unit 1632